

Of Note

Growing Human Kidneys in Rats Sparks Ethical Debate

The *American Journal of Transplantation* recently published findings from a study conducted by Eugene Gu, a medical student at Duke University and founder and CEO of Ganogen, Inc., and his colleagues. The study obtained kidneys from aborted human fetuses and implanted them into adult rats that lacked an immune system. A month later, the researchers removed the rats' own kidneys. The rats survived an average of four to five months and one survived ten months. Gu's team believes this research could lead to safer methods of drug testing and, ultimately, healthy kidneys for transplantation into humans. This type of research raises several ethical questions. Can researchers use human fetal organs at all and how is consent defined? Is it ethical to implant human organs into nonhuman animals? What kind of oversight is necessary when transplanting kidneys into animals? Arthur Caplan, a bioethicist at NYU Langone Medical Center, is not concerned about the study itself but about the reaction of the American public. "American society is morally uncomfortable enough about abortion that growing organs from fetal remains will never be accepted, and will be banned in state after state."

Tanya Lewis, Jan. 21, 2015,
Livescience.com

Diagnosis of Alzheimer's Disease Often Withheld From Patients, Report Says

The Alzheimer's Association recently released their 2105 Facts and Figures report. One finding indicated that only 45 percent of those with Alzheimer's were given their diagnosis by doctors or health care providers. The report stated two common reasons doctors withhold the diagnosis: a reluctance to create additional emotional stress and lack of time or training to properly diagnose the disease. Withholding the diagnosis gives families less time to make financial and caregiving plans and ignores the dignity and autonomy of the patient. The report notes that the negative public perception of Alzheimer's is the same as that of cancer decades before. It is estimated that in 2015, 5.3 million people are living with Alzheimer's disease. Direct cost of the disease is estimated at \$226 billion. Frederick Kunkle, March 24, 2015, *The Washington Post*

Insurers Squeezed By Aging's High Costs: Paying From Policies for Nursing Homes Draining Profits

In the 1980s, Genworth made incorrect assumptions concerning how long people live, the cost of health care and interest rates. These errors have led to Genworth raising prices on older long-term care policies and introducing new products to make long-term care insurance a sustainable business. Tom McNerney, Genworth's CEO, says "There's clearly a

very high need for these policies, given high demand and the limited number of insurers offering it today, I think it can be a very good industry going forward.” Genworth is not the only company having to make changes to its long-term care policies. Four of the five largest long-term care insurance providers have decreased their long-term care insurance or stopped selling any new policies. Outside of private insurance, older Americans have few options. Medicare only covers nursing home care stays in certain circumstances and long-term insurance is not part of the Affordable Care Act. Many people are turning to Medicaid to cover the costs but that puts a strain on state budgets. Long-term care insurance providers have learned from past errors and calculated a necessary price for policies but the price may be too high for most people to afford. Matthew Craft, March 29, 2015, *The Blade*

Teenagers Face Early Death, on Their Terms

A new guide, “Voicing My Choices,” has been created for and by adolescent and young adult patients as a way to discuss end-of-life issues and wishes. Lori Wiener, a social worker and principal investigator on the research that led to the guide, said it was created to give young patients a way “to make choices about what nurtures, protects and affirms their remaining life and how they wish to be remembered.” Although parents retain legal authority for underage patients, the guide asks questions regarding medical decisions and comfort preferences. Other sections

include a list of favorite things, visitor protocol and an opportunity for self-description. For some young patients, the guide allows them to assert control which can be therapeutic. The ability to designate their bodies for research and create a ritual for their funeral gives patients the ability to leave behind a legacy. When to give the guide to a patient is still a debated topic. Wiener suggests giving the guide to the patient soon after the diagnosis but when the patient is stable. Waiting too long can result in a patient being unable to physically voice their wishes. Some parents resist the guide because they fear talking about death will bring about death faster. Some patients resist the guide because they do not want to express their true feelings concerning treatment with their parents. Although the guide meets some resistance, it has proven beneficial to some young adults and their families. Jan Hoffman, March 28, 2015, *The New York Times*

Disabled Elderly Decline Sharply After ICU

A new study published in *JAMA Internal Medicine*, examined data on almost 300 patients to determine if disability level affected patient results after being admitted to the hospital intensive care unit (ICU). The study team used a questionnaire of basic life tasks to determine disability levels and accordingly grouped people into one of three categories: minimally disabled, mild to moderate disability, or severely disabled.

The study found that patients with mild to moderate disability were twice as likely as minimally disabled patients to die within one year of ICU hospitalization and the severely disabled patients were three times as likely to die within one year. The minimally disabled patients should be the focus for aggressive rehabilitation since they have the best chance of full ICU recovery. Dr. Lauren E. Ferrante, lead author, stated that surprisingly, “pre ICU function had the same magnitude of effect as a mechanical ventilator.” Dr. Kenneth Covinsky, a clinical-researcher in the University of California division of geriatrics, wrote an editorial to accompany the study. “This study shows that even among those who survive their care in the ICU, rates of disability are very high in the following year ... Older patients and their families need to be prepared for the likelihood that they will be considerably more disabled after an ICU stay.” Kathryn Doyle, Feb.12, 2015, *Reuters*

Transplant first: Organ Donation from UK Newborn

The parents of a six-day-old baby girl agreed to donate her kidney to a patient with renal failure and donate liver cells to a patient with a failing liver. The baby girl had severe brain damage and the intricate surgery occurred when her heart stopped beating. Professor James Neuberger, NHS Blood and Transplant, said “We are pleased the first transplant of organs from a newborn in the UK was a success and we praise the brave decision of the family to

donate their baby’s organs ... The sad reality is for everybody to get the lifesaving transplant they are desperately in need of, more families who are facing the tragic loss of their young child will need to agree to donation.” In the UK, the official waiting list has 15 infants under the age of two currently in need of organs but the numbers may actually be higher. For small children, organs from older donors do not always work but instead successful transplants come young children. The Royal College of Paediatrics and Child Health is conducting an official review. Smitha Mundasad, Jan. 19, 2015, BBC News

The Coming Revolution in Much Cheaper Life-Saving Drugs

In January, a Food and Drug Administration panel recommended the approval of Zarxio, a biosimilar drug of Neupogen, which helps cancer patients fight infection after chemotherapy. Zarxio would be the first biosimilar drug to be approved by the FDA. A biosimilar is similar to a generic drug but instead of being a copycat of a chemically synthesized medication it is a copycat of a biologic. Biologics are complex and costly drugs made from living organisms. The law requires that biosimilars are “highly similar” to the original drug and do not have any “clinically meaningful” differences. Generic drugs offer about 75 percent savings from the brand-name drug but biosimilars will probably offer a 20 to 30 percent savings. The FDA must also decide if biosimilars will require a unique

name or retain the name of the drug they are copying. There are a few factors influencing the approval of biosimilar drugs. Makers of biologics are looking to block approval as they try to protect their drugs and their profits. The health care industry wants approval because it could reduce spending. Those producing biosimilars are concerned about educating patients and doctors about this new drug category. Jason Millman, Jan. 16, 2015, *The Washington Post*

Online Offers of Personalized Cancer Medicine May Not Be Trustworthy

Dr. Stacy W. Gray, a medical oncologist at Dana-Faber Cancer Institute in Boston, is the lead author of a study recently published in the *Journal of the National Cancer Institute*. The researchers looked at 4,910 websites that promoted or sold personalized cancer medicine such as tumor tests and genetic risk analyses. Of the top 55 websites, 56 percent were commercially sponsored. Another 20 percent were promoted by academic institutions and 15 percent by private institutions. Only 2 percent were conducted by individual doctors. The researchers found that only 28 percent of the websites sold tests they would endorse. Most sites described the benefits of their products (85 percent) but only 27 percent specified possible limitations. Evaluating the website's validity is not easy because each site is unique from all the others. Dr. Gray told Reuters, "The take home message for patients and doctors is that they need to be careful and critically

evaluate what they see online. If patients encounter things online they're curious about, they should talk to their providers about whether those tests are helpful."

Janice Neumann, March 11, 2015, *Reuters Health*

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, Assistant Director, supervised the contributions of health law students Lauren Rodriguez (J.D. Anticipated May 2016) and Maxwell Murtaugh (JD anticipated May 2015).

Guatemalans Deliberately Infected with STDs Sue Johns Hopkins

Experiments similar to the Tuskegee syphilis experiments were conducted in Guatemala during the late 1940s and early 1950s. A lawsuit filed at the end of March 2015 against Johns Hopkins, the Rockefeller Foundation, Bristol-Myers Squibb and Mead Johnson alleges that vulnerable populations of Guatemalan citizens were infected with various sexually transmitted diseases [STD] in order to test the effectiveness of penicillin and other treatments against STDs. This lawsuit seeks more than \$1 billion in damages and follows the 2012 dismissal of a federal class action lawsuit regarding the same experiments but filed against the U.S. government. The lawsuit now pending in Baltimore City Circuit Court alleges Johns Hopkins and the Rockefeller Foundation not only designed, but they

benefitted from the experiments by controlling and influencing the authorized individuals directly dealing with the research of venereal disease.

Ralph Ellis, CNN, April 4, 2015, <http://www.cnn.com/2015/04/03/americas/guatemala-std-lawsuit/index.html>.

Giving Out Private Data for Discount in Insurance

John Hancock Insurance is introducing a program that will apply a consumer's day-to-day fitness activities and health information to the consumer's life insurance policy. This program will be operated in conjunction with global wellness company, Vitality. It is well-known anyone buying life insurance will need to share her medical history, but this program will also ask customers to provide continuous updates on health and fitness activity. John Hancock's program will be a point-based discount and incentive program that might have its consumers answer more personal and sensitive health information to collect points and earn insurance premium discounts. The president of John Hancock Insurance, Michael Doughty, said consumers do not have provide information they don't want to, "[t]he trade-off is you won't get points for that." Questions of whether wellness program address the chronically ill population are already causing speculation of program value. Skepticism as to how the information collected by wellness programs will be protected is apparent as well. John Hancock clarified that the information gathered would not be sold

but it would be shared with entities assisting with the program's administration and could be used to develop new insurance products. Tara Siegel Bernard, *The New York Times*, April 8, 2015, <http://www.nytimes.com/2015/04/08/your-money/giving-out-private-data-for-discount-in-insurance.html?ref=health>.

DOJ Settles With Embattled Lab, Criminal Charges for Executives Still Possible

From a \$47 million payment to a possible \$100 million over time, Health Diagnostic Laboratory, Inc. (HDL) has reached a settlement agreement with the Department of Justice (DOJ) from an investigation dealing with kickbacks, illegal sales, marketing and billing practices. "When health care companies pursue profits by paying kickbacks to doctors, they undermine a patient's ability to trust that medical decisions are being made for scientific reasons, not financial ones," said District of Columbia Acting US Attorney Vincent Cohen Jr. Cohen also said this case demonstrates DOJ's committed to working with whistle blowers to "defend the integrity of the health care system from illegal agreements that hurt patients and taxpayers." Larry Husten, *Forbes*, April 10, 2015, <http://www.forbes.com/sites/larryhusten/2015/04/10/doj-settles-with-embattled-lab-criminal-charges-for-executives-still-possible/?ss=pharma-healthcare>.

Health Insurers May Be Finding New Ways to Discriminate Against Patients

In 2014, two patient advocacy groups filed a discrimination complaint with the Department of Health and Human Services' civil rights division accusing four Florida insurers of forcing "HIV patients to pay up to 50 percent of the cost of HIV medications, even for generic versions." The four insurers were selling their plans on the ACA exchanges, and under the ACA, health insurers cannot charge individuals more or avoid covering them due to preexisting conditions. The idea is that instead of denying sick patients, insurers placed more expensive medications "for certain chronic conditions into the highest-priced tiers of the drugs they cover," which could cause patients to pay a lot more out of pocket. If true, this means health insurers are creating insurance plans with drug benefits designed to "dissuade sicker people from choosing their plans." Some critics of this attack on insurers point out that everyone has access to coverage and that consumers have a wide range of choices to consider when selecting a plan. All plans are also reviewed by both state and federal officials, and one aspect of the review is identifying any discrimination occurring in plans through benefit designs that "discourage enrollment of consumers with specific medical conditions." While the Obama administration has indicated that it would be considered discriminatory for insurers to design plans that place most drugs for specific conditions into the highest tier of costs, there are calls for

stricter enforcement of these standards. Jason Millman, *The Washington Post*, Jan. 28, 2015

<http://www.washingtonpost.com/blogs/wonkblog/wp/2015/01/28/health-insurers-may-be-finding-new-ways-to-discriminate-against-patients/>

Eight State Legislatures Debate Adoption of Interstate Medical Licensure Compact

Eight state legislatures are considering passing uniform legislation that would essentially "make it easier for physicians to acquire licenses in multiple states." These states are Iowa, Minnesota, Nebraska, South Dakota, Texas, Utah, Vermont, and Wyoming. So far, bills have been introduced that if passed would adopt the Interstate Medical Licensure Compact. The final model of the compact was released in September, 2014, and now, in 2015, states are beginning to seriously consider adopting this legislation. The goal is to "streamline interstate licensing" by allowing physicians in a member state to "apply through the compact for expedited licensure in any member state." The way the compact would work is a licensed physician would submit an application to an interstate commission to practice in another member state. The commission would then determine licensure eligibility. If the physician passed the review and paid the applicable fees, they would be issued a license to practice medicine in that particular member state. Advocates for enactment believe the compact protects the public while being a

more effective mechanism compared with the often rigorous licensing rules currently in place. The overarching goal is to create a licensure system that can cater to the needs of “a growing and changing health care market.” Bloomberg BNA 24 Health Law Reporter (HLR) 123, Jan. 29, 2015, http://healthlawrc.bna.com/hlrc/4237/split_display.adp?fedfid=62153082&vname=hlrnotallissues&jd=a0g1t3u0c9&split=0

UK Lawmakers Approve '3-parent babies' Law

Lawmakers in the United Kingdom approved a proposed law that would make them the “first country...to allow a pioneering in vitro fertilization technique using DNA from three people.” However, there still needs to be a vote in the United Kingdom’s upper house before the bill can officially become law. The pioneering technique carries with it the potential benefit of preventing mitochondrial diseases which affect one in 6,500 babies in the United Kingdom and which can cause health issues including blindness and heart disease. Mitochondria problems are passed down from the mother so the technique would allow mothers to have children without passing on the disease. The technique would involve “transferring nuclear genetic material from a mother’s egg or embryo into a donor egg or embryo that’s had its nuclear DNA removed.” The new embryo would then essentially create a “three-parent baby” composed of nuclear DNA from both parents and “healthy mitochondrial DNA from the donor embryo.” Proponents of the law

stress that mitochondrial diseases cannot be cured and can affect several people within a family. Additionally, the procedure does not affect the “child’s appearance, personality, or any other features that make a person unique.” However, the proposal is opposed by some religious leaders “in part because the process involves the destruction of an embryo.” The Church of England understands the importance of this procedure and mitochondria diseases, but is calling for more research and discussion on the matter before “such a serious step” is taken. Laura Smith-Spark, CNN, Feb. 3, 2015, <http://www.cnn.com/2015/02/03/health/uk-ivf-3-person-babies/index.html>

Supreme Court Justices Split in Key Challenge to Obamacare Subsidies

Supreme Court justices appeared to “split along ideological lines” during oral arguments in the case of *King v. Burwell* which involves a challenge to ACA tax subsidies. The challengers argued that a “straightforward reading of the law,” which includes the phrase, “established by the State,” requires individuals to purchase insurance on state marketplaces in order to receive tax subsidies. This interpretation means that individuals purchasing plans on federal marketplaces would not be eligible for tax subsidies. A ruling in favor of this meaning could have a major impact on the millions of “Americans who receive subsidies in the 34 states” that have declined to set up state-run exchanges. The liberal justices

suggested that the law's requirement for federal authorities to setup exchanges when states have declined to do so clearly indicates that "the subsidies follow;" otherwise the ACA's goal of universal health care would be impossible. This line of argument focused on placing, "established by the State," in the context of the ACA as a whole. The conservative justices, on the other hand, asked why did Congress use this specific terminology instead of "under this the act" if it did not intend for it to literally mean "by the State." They focused on implementing the actual statute as written and not twisting words to achieve the statute that Congress intended to create. While the decision will have a major impact on the ACA's viability, a final decision will likely not be ready until sometime in June. Robert Barnes, *The Washington Post*, March 4, 2015

http://www.washingtonpost.com/politics/courts_law/obamacare-back-before-high-court-today/2015/03/03/6dff31a4-c1ec-11e4-9271-610273846239_story.html

Missouri Health Care Navigator Law Pre-empted, Court Rules

The 8th Circuit Court "blocked some parts of a Missouri law" which restricted the type of information navigators and certified counselors could provide to those trying to obtain health insurance under the ACA. This ruling was in response to a challenge to a 2013 Missouri law that prevented navigators and certified counselors from giving advice on choosing an insurance plan. The law also prevented

counselors from talking about plans that were not on the federal website and required "counselors to direct consumers who have had insurance through an agent or broker to talk to an insurance provider instead." This essentially reduced the amount of assistance counselors and navigators could give to those trying to find health insurance. The 2013 restrictions created a situation of uncertainty where many counselors were unsure what information qualified as prohibited advice such as whether advising people to apply for Medicaid would violate the law. The 8th Circuit held that these limitations conflicted with and thus were superseded by federal law which permitted such advising. The court did find, however, that Missouri could implement "licensure requirements for navigators and counselors," but they could not limit or control the type of information discussed or provided. While this ruling is Missouri-specific, many hope that other states will follow this lead. Associated Press, *The New York Times*, April 10, 2015
http://www.nytimes.com/aponline/2015/04/10/us/ap-us-xgr-health-overhaul-navigators.html?_r=0